K010770

SIMS A SMITHS GROUP COMPANY

BCI

JUN 1 2 2001

Summary of Safety and Effectiveness

Submitter:	SIMS BCI, Inc.
Address:	N7 W22025 Johnson Road Waukesha, WI 53186
Telephone:	(262) 542-3100
Contact:	VP Regulatory Affairs
Prepared:	March 5, 2001
Proprietary Name:	BCI™ Advisor® vital signs monitor (model 9200) with new neonate mode
Common/Classification Name:	Vital signs monitor
Predicate Devices:	BCI 9200 vital signs monitor (K982279) BCI 6004 NIBP monitor (K984618) BCI 6200 vital signs monitor (K953415) HP Viridia M3/M4 Monitor M3046A, Viridia Measurement Server M3000A (K971910, K981579)

New Device Description:

The BCI 9200 vital signs monitor has been updated to include a new neonatal mode which uses the same technology as existing legally marketed devices. This device is designed to provide full featured monitoring capabilities in a table top design. The full system features an ECG cable interface, two invasive pressure interfaces, two YSI 400/700 compatible temparature interfaces, an NIBP cuff hose connection, an SpO_2 sensor interface, an internal printer, display of patient and waveform data via a color liquid crystal display (LCD), system power status LEDs, a rotary control knob and the function keypad area consisting of five keys (on/off, IP zero, NIBP start/stop, print start/stop and alarm silence). The monitor has a serial port that is used for data communications.

Intended Use:

The 9200 vital signs monitor is intended to be used in the ICU, CCU, OR, ER, RR, Labor and Delivery rooms, special procedure labs and other areas of the hospital or clinic where low end monitoring systems are needed. The basic monitor package includes ECG (3 lead / 5 lead), impedance respiration (RSP), non-invasive blood pressure (NIBP), pulse oximetry

(SpO2), two invasive blood pressures (P1 and P2), and two temperature channels (T1 and T2). A two-inch internal, graphical/alphanumeric printer and a battery are provided as options. The device permits patient monitoring with adjustable alarm limits as well as visible and audible alarm signals. The device will provide fast, reliable measurements on patients ranging from neonate to adults when using the appropriate BCI accessories. The respiration parameter is available only in the adult mode and is not intended for neonatal monitoring.

The monitor is not intended for home use. The monitor is not intended to be an apnea monitor. It was not designed or validated for use as an apnea monitor.

Performance Data:

The design of this device utilizes currently available technology found in many legally marketed devices. Testing was done previously to ensure that the BCI 9200 monitor would perform within the environment(s) for which it is to be marketed (K982279). As only software has changed, further environmental testing was not necessary. The previous testing was performed in accordance with the guidelines and standards found in the reviewer's guides for respiratory devices (November 1993). Electromagnetic compatability (EMC), electrical, mechanical durability, safety (operator and patient), and temperature/humidity testing has been completed. The results demonstrated that the BCI 9200 monitor was in compliance with the guidelines and standards referenced in the reviewer's guides and that it performed within its specifications and functional requirements.

Additional safety testing of the new neonatal NIBP mode was performed in accordance with IEC 601-2-30: 1995. The monitor fulfills the requirements of the standard.

A full software validation test of the 9200 with the new neonate NIBP mode was completed. This test showed that the device works as intended in both adult and neonate mode.

Comparison of the adult mode portion of the new device's software validation test to previous software validation tests of the 9200 vital signs monitor demonstrates that the adult mode parameters were not affected by the addition of the neonate mode. The tests were run using patient simulators with settings spanning the 9200's entire specification range for ECG, respiration, adult NIBP, IBP, SpO_2, and temperature. All measurements were within the specified tolerances of the monitors and simulators. These data support substantial equivalence of the ECG, respiration, NIBP, oximetry, invasive pressure, and thermometry parameters of the new 9200 monitor running in adult mode to the predicate 9200 monitor.

Validation of the new neonate mode was performed by testing to performance standards and comparison to devices legally marketed for neonatal use.

Clinical testing of the BCI 9200 vital signs monitor with new neonatal mode demonstrated compliance of the NIBP parameter to the ANSI/AAMI SP10-1992 standard (American National Standard for *Electronic or automated sphygmomanometers*) and ANSI/AAMI/ISO SP10A-1996 Amendment to ANSI/AAMI SP10-1992. The SP-10 testing was conducted after receiving Institutional Review Board (IRB) approvals at two local hospitals on neonates

ranging in size from 0.455 to 3.5 kilograms. Measurements of systolic, diastolic, and mean arterial blood pressures made by the 9200 monitor's algorithm were compared to measurements made from an arterial line pressure transducer. The means of these differences are: 0.1 mmHg for systolic pressures, -1.4 mmHg for diastolic pressures, and –1.4 mmHg for mean arterial pressures. These fall within the ±5 mmHg limit imposed by the SP-10 standard. The standard deviations of these differences are: 6.8 mmHg for systolic pressures, 5.8 mmHg for diastolic pressures, and 5.4 mmHg for mean arterial pressures. These fall within the 8 mmHg limit imposed by the SP-10 standard.

The previous 510(k) submission also included data demonstrating the compliance of the 9200's ECG parameter to AAMI EC13-92, Cardiac monitors, heart rate meters, and alarms. The monitor met all of the standard's requirements for both adult and neonatal use at the time of the previous submission. In neonate mode, the ECG parameter is the same as it is in adult mode with the exception of default settings. These default settings include alarm limits and three lead operation.

The invasive pressure and thermometry parameters work the same in neonate mode as in adult mode with the exception of default alarm limits. The expected ranges for pressures and temperatures are the same for adults and neonates. Comparative data demonstrating the equivalence of the 9200 in neonate mode to a predicate device was obtained using patient simulators and is presented in Section 5.

The pulse oximetry parameter works the same in neonate mode as in adult mode with the exception of default alarm limits. The pulse oximetry parameter was previously clinically validated in adults (K982279). In addition, comparative data between the 9200 in neonate mode and a predicate device have been collected on neonatal subjects. These data demonstrate the equivalence of the two devices and are presented in Section 5 of this 510(k).

The testing described above indicate that there is no functional difference between the operation of the 9200 vital signs monitor with new neonatal mode and the predicate 9200 vital signs monitor for adult mode ECG, respiration, NIBP, oximetry, invasive pressure, and thermometry measurements. The testing described above also indicates: that there is no functional difference between the operation of the 9200 vital signs monitor with new neonatal mode and the 6004 NIBP monitor for neonatal NIBP measurements; that there is no functional difference between the operation of the 9200 vital signs monitor with new neonatal mode and the 6200 vital signs monitor for neonate mode ECG, oximetry, and thermometry measurements; and that there is no functional difference between the operation of the 9200 vital signs monitor with new neonatal mode and the HP Viridia monitor for neonate invasive pressure measurements. The clinical data also provide information on the accuracy of the new neonatal NIBP function.

On the basis of these results, it is our determination that the device is safe, effective, and performs as well as the legally marketed predicate device(s).

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Respectfully,

Donald Alexander

Donald Alexander
VP Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2001

Mr. Donald J. Alexander
SIMS BCI, Inc.
N7 W22025 Johnson Road
Waukesha, WI 53186

Re: K010770
Trade Name: BCI 9200 Vital Signs Monitor
Regulation Number: 870.2300
Regulatory Class: II (two)
Product Code: MWI
Dated: March 5, 2001
Received: March 14, 2001

Dear Mr. Alexander:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K010770

Device Name: BCI 9200 Vital Signs Monitor with Neonate Mode.

Indications For Use:

Intended Use

The 9200 vital signs monitor is intended to be used in the ICU, CCU, OR, ER, RR, Labor and Delivery rooms, special procedure labs and other areas of the hospital or clinic where low end monitoring systems are needed. The basic monitor package includes ECG (3 lead / 5 lead), impedance respiration (RSP), non-invasive blood pressure (NIBP), pulse oximetry (SpO_2), two invasive blood pressures (P1 and P2), and two temperature channels (T1 and T2). A two-inch internal, graphical/alphanumeric printer and a battery are provided as options. The device permits patient monitoring with adjustable alarm limits as well as visible and audible alarm signals. The device will provide fast, reliable measurements on patients ranging from neonate to adults when using the appropriate BCI accessories. The respiration parameter is available only in the adult mode and is not intended for neonatal monitoring.

The monitor is not intended for home use. The monitor is not intended to be an apnea monitor. It was not designed or validated for use as an apnea monitor.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010770

Prescription Use X OR Over-The_Counter Use _____
(Per 21 CFR 801.109)